Clearing Up the Confusion: Why a Tuberculocidal Claim on a Surface Disinfectant Is No Longer Needed

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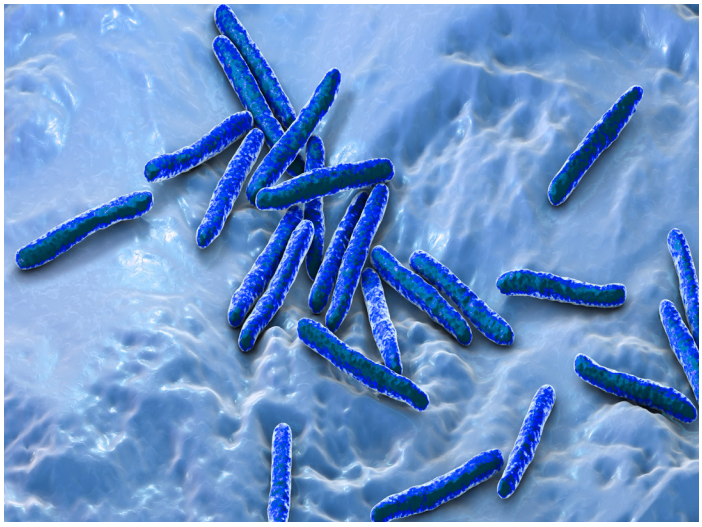

Cleaning and disinfecting are commonly performed using a manual trigger spray bottle and wiping. For decades, tuberculocidal disinfectants, designated intermediate-level disinfectants, have become an accepted standard for disinfectants in infection prevention and control guidelines.[1] However, our research has shown that there are no current requirements for healthcare disinfectants to have a tuberculocidal ("TB") claim. Given this, it is our position that the intermediate-level, tuberculocidal claim is no longer relevant in today's regulatory and clinical environment and is not needed for surface disinfectants. In this whitepaper, we provide evidence to support this position.

In 1972, Earl Spaulding, a microbiologist at Temple University formalized definitions of disinfection levels — low, medium, and high — based on the intrinsic resistance of microorganisms to disinfectants.[1] Spaulding described intermediate-level disinfection as the level required to inactivate *Mycobacterium tuberculosis*, a bacterium that is intrinsically resistant to disinfection. Low-level disinfection, intended for surfaces and non-critical medical equipment, is not expected to inactivate *Mycobacterium tuberculosis*. Spaulding also grouped medical equipment and devices into four categories and assigned an appropriate level of disinfection for each based on the infection risk involved in their use (Table 1). The Spaulding classification system forms the basis for disinfection and sterilization practices in healthcare today.

Table 1. Classification of Types of Medical Equipment and Devices and Level of Disinfection Required*

EQUIPMENT, DEVICE OR SURFACE	DESCRIPTION	EXAMPLE(S)	LEVEL OF DISINFECTION
CRITICAL	Contacts normally sterile tissue	Surgical instruments	Sterilization
SEMI-CRITICAL	Contacts mucous membranes or non-intact skin	Anesthesia equipment, tonometer	High
NON-CRITICAL	Contacts intact skin	ECG machines, pulse oximeters, bed frames	Intermediate or low
ENVIRONMENTAL	Inanimate surfaces	Floors, counters, door handles	Intermediate or low

*Table based on CDC & HICPAC Guidelines for Environmental Infection Control in Health-Care Facilities. 2003, updated 2019. Available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf Accessed September 1, 2022.

In the hierarchy of microorganism susceptibility to germicides, mycobacteria are particularly resistant to chemical disinfection, with only bacterial spores, such as *Clostridioides difficile*, being more resistant (see Figure 1). At the opposite end of the spectrum, enveloped viruses, such as human immunodeficiency virus (HIV) and hepatitis B virus (HBV), with their lipid outer coat are the least resistant—and therefore most susceptible to disinfectants. The Centers for Disease Control and Prevention (CDC) Guidelines to Prevent the Transmission of Tuberculosis[2] emphasize that the purpose of a tuberculocidal claim on a disinfectant is a benchmark of antimicrobial efficacy, and is not for the control or prevention of transmission of tuberculosis, an airborne-spread disease that is not transmitted via contaminated surfaces. Unlike in 1972, healthcare facilities in today's marketplace have a wide variety of disinfectants to choose from, including those with HIV, HBV, and bacterial spore kill claims that may not have a tuberculocidal claim on label. The perceived requirement of a tuberculocidal claim may limit disinfectant choice and could result in selection of a product with properties that are not ideal in terms of compatibility, acceptability, and contact time.

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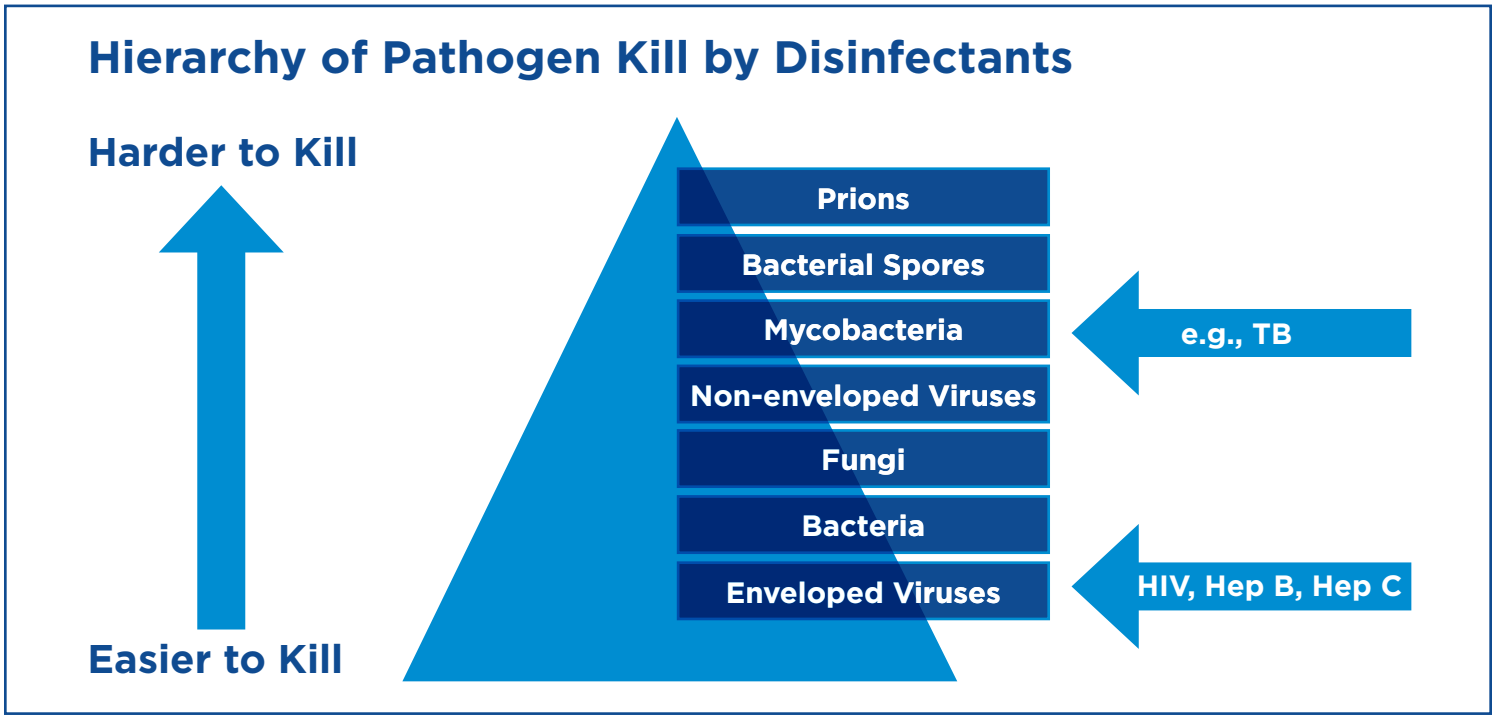

Figure 1. Hierarchy of Pathogen Kill by Disinfectants

To shed light on the confusion surrounding the perceived intermediate-level tuberculocidal claim requirement, we surveyed 50 healthcare-associated infection (HAI) state coordinators about whether they knew of regulations in their own state that required healthcare disinfectants to carry a tuberculocidal claim. We received three types of responses from 18 states:

- Disinfectants used should be appropriate for the type of pathogen or microorganism
- Each hospital or healthcare organization must determine which disinfectant is appropriate
- Facilities should follow Occupational Safety and Health Administration (OSHA), CDC, and Environmental Protection Agency (EPA) guidance for cleaning and disinfecting.

We reviewed public information for a further seven states. In total, across 25 states we found no evidence that disinfectants are required to carry a tuberculocidal claim in healthcare settings.

The uncertainty surrounding the tuberculocidal requirement can be traced back to the 1990's, when OSHA defined an "appropriate" disinfectant for blood or body fluid spills as one with a tuberculocidal claim or bleach solutions of a specific concentration (Figure 2). The use of a tuberculocidal, or intermediate-level disinfectant was reasonable given the expected efficacy of such a disinfectant against the bloodborne enveloped viruses, HIV and HBV.[3,4,5] However, in 1997, in response to inquiries from disinfectant manufacturers with the EPA label claims against HIV and HBV, OSHA revised its description of an "appropriate" disinfectant to include "EPA-registered disinfectants that are labeled as effective against HIV and HBV".[6] This Standards Interpretation effectively eliminated the requirement to use a tuberculocidal disinfectant to comply with the bloodborne pathogens standard. Current OSHA guidance is clear; to comply with the Bloodborne Pathogens Standard—a federal regulation—low-level disinfectants with label claims against HIV and HBV can be used; disinfectants do not need to be tuberculocidal.

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Additionally, the CDC Guidelines for Environmental Infection Control in Healthcare Facilities Settings (2008)[7] clearly indicate that a low-level disinfectant can be used to disinfect non-critical and environmental healthcare surfaces. Furthermore, if the low-level disinfectant has HIV and HBV label claims, it can also be used to disinfect surfaces that have been contaminated with blood, bodily fluids, or other infectious material. This guidance further demonstrates that an intermediate-level disinfectant requirement is not needed in healthcare settings.

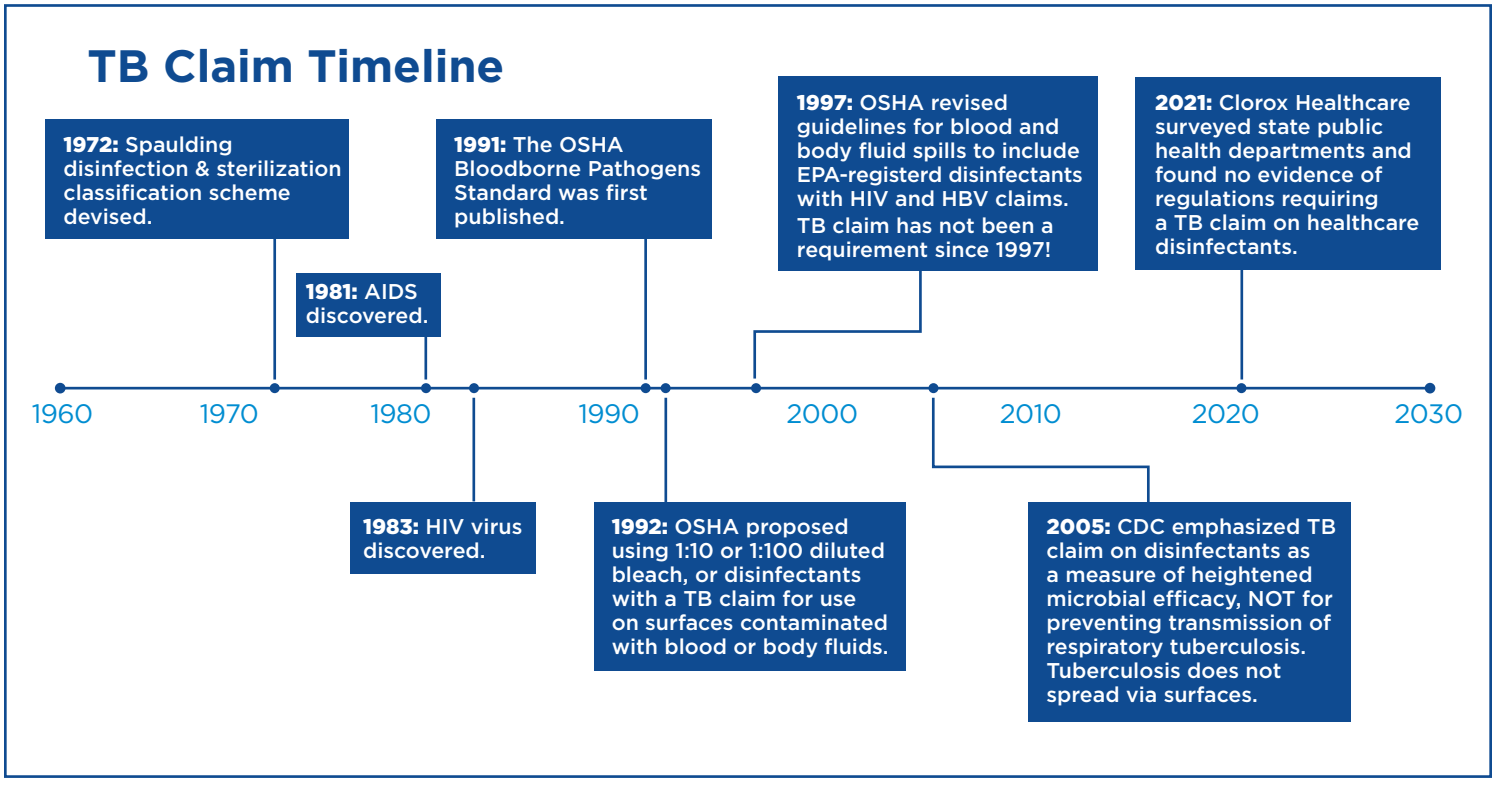

Figure 2. TB Claim Timeline

Our review of federal regulations and agency guidelines found that an intermediate-level, tuberculocidal disinfectant is not required in healthcare settings, either by federal or state regulators, nor by widely adhered to agency guidelines. Our findings clearly support our position that an intermediate-level, tuberculocidal disinfectant is neither indicated nor required in today's healthcare environment. Requiring only disinfectants with tuberculocidal claims is limiting the choice of appropriate disinfectants available. Healthcare facilities should instead look for disinfectants with EPA-registered claims against relevant microorganisms of concern, such as those that cause HAIs and bloodborne diseases.

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